REMARKS

Reconsideration is hereby requested as is a two-month extension of time within which to respond to the Official Action of January 2, 2002. The extension of time fee therefore ($200) for a Small Entity is to be charged to Deposit Account No. 502557.

Responsive to the Examiner's claim objections of ¶1 and rejections under §112 of ¶¶2-3 of the Official Action, Claim 6 has been cancelled, and Claims 9, 14, and 17-19 have been amended.

Claims 5, 9, 14, 18, and 19 have been rejected under 35 U.S.C. 102(b) as anticipated by Branemark, et al (U.S.P.N. 4,330,891), this on the basis that Branemark discloses an element with a micro-pitted surface for the growing of tissue of a particular type. While Branemark relates that his pit size has an upper limit which corresponds to that of certain cell diameters, the process of micro-pitting to form a "micro-pitted surface" that is taught by Branemark relates to a surface pattern which is inherently random in character. Further, even if Branemark did have in mind a particular surface pattern for his micro-pitted surfaces, that pattern is not suggested in any manner in his specification which does not contain any drawings. That is, notwithstanding the language of the Abstract (Lines 19-21 thereof) that the

micro-pitted surfaces of Branemark may include elements that "may be shaped with grooves, corrugations, channels, etc, and be provided with an opening for tissue to grow through" still does not provide any specific suggestion of order, directionality or the like, much less a repetitive surface pattern as is taught by Applicants. Further, while no teaching any type of repetitive surface pattern, given that 1000 nanometers equal 1 micron, the uppermost range of the magnitude of the micro-pits (or other structure) suggested by Branemark is but one-half of the low end (two microns) of the Applicants range (2-25 microns) of repetitive parallel alternating ridges and grooves. As such, most of the range of 10-1000 nanometers of Branemark constitutes a surface far too smooth to produce an orientation and directionality of growth of colonies of cells having sufficient contact with an implant surface. Further, Branemark notes (Col. 2, Line 41 thereof that his preferred range is 10 to 30 nanometers (0.03 microns))thereby falling well below the low end of Applicants' range of dimensions. It is, thereby, to be appreciated that not only is the order of magnitudes of the "pits" of Branemark below that of Applicants' claimed range but, in addition, there is no teaching of the use of a repetitive surface pattern of any type, notwithstanding Branemark's comments that his elements may be shaped with grooves, corrugations, channels and the like. In fact, it is unclear from such language whether Branemark simply intends that his micro-pitted surface can be applied to an implant having grooves, corrugations and channels or, alternatively, whether or not such grooves, corrugation and channels are the micro-pits. That is, Branemark apparently uses the

term "element" to mean implant and that the implant may have both grooves and micro-pits

With further regard to the Abstract of Branemark, it is noted, at Line 9 thereof that "Optimal result are obtained with pore diameters equal to or smaller than 300 nanometers..." which is consistent with Branemark's recitation of the 10 to 300 nm range in Col. 2, Line 41 of his specification. Therein, it is also clear that Branemark equates a pore o a micro-pit. It is also clear that the pore size of Branemark is at its high end, one-half of the low end of the range of Applicants and, at its low end, .005 of the low end of Applicants' range. This fact taken in combination with the complete absence of any enabling teaching as to whether or not Branemark contemplated any form or repetitive surface pattern in that range, whether with or without grooves, corrugations, or channels, renders Branemark inoperative as a teaching or anticipatory reference.

Claims 5-7, 9 and 12-19 have been rejected under 35 U.S.C. 102(e) as anticipated by Naiman, et al (U.S.P.N. 5,607,607). Applicants however have submitted the declaration of co-inventor John L. Ricci (see Declaration of November 23, 2001) in regard to Application Serial No. 09/500,038, which was furnished as an enclosure to Applicants' response of October 8, 2002. This declaration indicates that the present invention was conceived years prior to the effective date (November 1, 1993) of Naiman. See ¶5 and ¶6 of said Declaration. Thereafter, the invention of this

Application was constructively reduced-to-practice on its effective priority date, that is, November 2, 1993, one day after the effective date of Naiman. As such, Naiman '607 cannot stand as a reference with respect to Claims 5-7, 9 and 12-14. In addition, these claims should be allowable by reason of their dependency from an allowable higher order claim, namely, Claim 14, this for the reasons discussed herein.

In the Official Action of January 2, 2003, Claims 5-7, 9, 14-16 and 19 were rejected under 35 U.S.C. 103(a) as unpatentable over Lin (U.S.P.N. 4,778,769) in view of Mears (U.S.P.N. 4,553,272). Therein, the Examiner appears to rely upon Mears teaching of the use of "open pores of an average size of about 25 to 75 microns and a second series of open pores of average size of about 100 to 400 microns..." (See last sentence of Abstract of Mears). However, Applicants, as above noted, do not employ pores but, rather, employ a specific repetitive surface pattern in the form of multiplicity of substantially parallel ridges and grooves, each having an established width in a range of about 2 to about 25 microns and an established depth within a like range of dimensions. Accordingly, neither the geometry nor the dimensionality of Mears is congruent with that of the Applicants. Further, the teaching of Mears does not relate to an orthopedic implant but, rather, to one which addresses issues of soft tissue, namely, cartilages, tendons, ligaments, and musculo-tendenous cells which, while relative to certain areas of joint reconstruction, do not relate an implant for the surgical insertion into a bone or bone-related tissue of a patient.

From the illustration of Fig. 1 of Mears, it is clear that use of thereof is contemplated to re-establish a ball-and-socket hip joint of a patient. This may be fairly compared to Fig. 20 of Applicants' specification in which, as may be noted, the Applicants' micro-geometric repetitive surface pattern is applied to the stem 106 and shoulder 110 of a hip implant but not to ball portion 130 thereof which is the area to which Mears would have application.

Further, from the enlarged radial cross-sectional view of Fig. 2 of Mears, the lack of order to the pores 12 of Mears is that of also apparent, as is that of pores 44 and 46 of Figs. 3 and 5 in which Mears shows in a dental application in his soft tissue implant. It is further noted that the only actual teaching of Mears is that his pores occupy between about 20 and about 50 percent of the total volume of the portion of the implant upon which they are used. (See Col. 3, Line 59 to 63). Accordingly, there is no order or pattern in the use of the open pore geometry of Mears other than that their total volume occupy 20 to 50 percent of the volume of the implant surface to which they are applied.

With regard to the reference to Lin, which the Examiner has applied as a teaching reference in the combination with Mears, it is respectfully noted that Lin relates to a dissolvable spacer used in a calcium sulfate acid etch process upon a plastic surface. Thereby, the acid etch mask and process of Lin is not applicable to high density materials such as titanium, stainless steel, ceramics, Hench glass and combinations thereof employed as a base material in Applicants' implant. The

present application makes reference to such high density base material of the implant in Claims 5 and 18 of the application. As noted by Applicants at Page 7, ¶1 of the specification, Lin employs an acid soluble spacer which contains a pattern to be transferred to the implant surface which, as such, is positioned upon a desired portion of the implant surface to be texturized. The spacer is then pressed into the implant surface and is then removed by treating it with an acid. This process, as above noted, is not applicable to the high density materials which must be employed in any orthopedic application of Applicants' invention.

In addition to the above, Lin and Mears, however combined, do not teach an essential limitation of Applicants invention, namely, a repetitive surface pattern in the form of multiplicity of *substantially parallel alternating ridges and grooves.* That is, as may be seen in Figs. 1-3 of Lin, the geometry thereof is not one of substantially parallel ridges and grooves but, rather, is one more akin to a honeycomb pattern. This pattern is described by Lin at Col. 2, Lines 53-56 to the effect that "pattern 14 includes tapered post 16 with undercuts 18 as well as pyramids 17 and triangular ridges 19, as shown in Figs. 3 and 5." The process by which this rather complex geometry is formed is further described by Lin at Col. 3, Lines 17-19 thereof. As such, Mears does not teach the use of substantially parallel pattern of alternating ridges and grooves. (Clearly, the grooves of Lin are not parallel to each other). And certainly, do not suggest any dimensionality whatsoever. Thereby, Lin and Mears, however combined, do not teach a high density implant element having the

limitations of dimension and geometry claimed by Applicants. In fact, these limitations are critical in the accomplishment of the objects of the invention, as is set forth in Applicants' Declaration under 37 C.F.R. 1.132 (combined with said 1.131 Declaration) furnished as Enclosure 4 with Applicants Amendment/Response of October 8, 2002. Therein, the remarks made relative to Wagner (U.S.P.N. 5,989,027) in ¶¶10-13 of said Declaration which relate to an essentially random, irregular porous surface, are equally applicable to the random open pore structure of Mears. For the above reasons, the references to Lin and Mears, however combined, do not anticipate or render obvious the limitations of Applicants' Claims 5-7, 9, 14-16 and 19.

With regard to the Examiner's "Response to Arguments" of Applicants, Applicants urge that a dictionary definition of the term "repetitive" that is not appropriate given that the Applicants have presented a lengthy specification, including many illustrations, to define their use of the term "repetitive" in the context of their invention (See for example Fig. 7 thru 14A of the Drawings and the description thereof at Pages 20-23 of the specification).

With respect to the Examiner's assertion that "a micron is such a small unit of length, 1.0 micron (1000 nanometers)" that it will fall within the range of "about 2

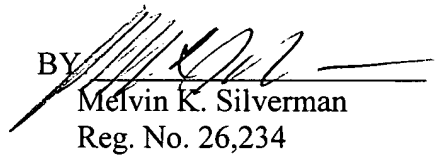
microns," Applicants are amenable to deletion of the term "about" prior to "2 microns" if the same would resolve the larger issue of patentability of Claim 14.

With further respect to Applicants' said Declaration filed under 37 C.F.R. 1.131 and Expert Opinion under 37 C.F.R. 1.132, John Ricci is a common inventor with respect to the present application, U.S. Patent No. 6,419,491, and the original 1993 patent application. Naiman in turn is a common inventor as between the presently pending application, the '993 parent and his '607 patent. Ricci therefore, as a co-inventor with Naiman, of the present application, its 1993 parent and the '491 patent was appropriately positioned to know of Naiman's work with Lamson relative to the invention of the '607 patent. This is particularly set forth in ¶¶1-4 of said Declaration. Further, Naimam '607 has not been cited as a basis of rejection of any independent claim extant in this Application. With respect to the operation of said Declaration under 37 C.F.R. 1.131 to prove conception prior to the effective date of Naiman '607, the Examiner (at ¶9, Page 6 of the Official Action) adopts a very narrow construction of Applicants' independent claim while adopting a more expansive construction thereof for purposes of the above-discussed rejections under Branemark, Lin and Mears. As such, if the invention is narrowly construed for purposes of Applicants' Declaration under 37 C.F.R. 1.131 and 1.132, it must be similarly narrowly construed with regard to the rejections of record under §102 and §103.

With regard to the Examiner's the Examiner's issue with regard to the phrase "about 25 microns," Applicants are amenable were to deletion of the term "about" from the recited range of dimensionality in independent Claim 14. As such, the Examiner is urged to contact Applicants if the limitation of "about 2 to about 25 microns" in favor of --2 to 25 microns,-- would resolve the remaining issues of patentability in this matter. Such a proposed independent claim is attached herewith.

In view of the above, all objections and rejections of record are believed to have been satisfactorily responded to and, as such, the early allowance of this Application is believed to be indicated.

Respectfully submitted,
JOHN L. RICCI, et al

BY 
Melvin K. Silverman
Reg. No. 26,234

MELVIN K. SILVERMAN
500 WEST CYPRESS CREEK ROAD
SUITE 500
FORT LAUDERDALE, FL 33309
TELEPHONE (954) 351-7474
FACSIMILE (954) 492-0087
E-mail: mks@powerlaw.net

Enclosures:
1. Marked-up and Newly Amended Claims.
2. Proposed new independent claim.
3. Notice of Change of Address.

Marked-up and Newly Amended Claims for Serial No. 09/784,284

5. (previously amended). The implant as recited in Claim 14 in which base materials of said implant are selected from the group consisting of the materials of titanium and alloys thereof, stainless steel, ceramics, biocompatible glass and combinations thereof.

[6. The implant as recited in Claim 15 in which said orthonormal matrix is oriented diagonally relative to a major axis of the implant.]

7. (previously amended). The implant as recited in Claim 14 in which said repetitive micro-geometric pattern of ridges and grooves comprises application to surfaces of said implant element in orientations which, relative to a longitudinal axis of said implant, are selected from the group consisting of vertical, horizontal, orthonormal diagonal, radial, circumferential, and concentric orientations.

9. (newly amended). The implant as recited in Claim 1 in which said orthopedic implant is selected from the group consisting of hip, knee, shoulder, elbow, ankle and finger implants.

12. (original claim). The implant as recited in claim 9 comprising different zones furnished with respectively different surface patterns.

13. (original claim). The implant as recited in Claim 12 in which said different zones include respective hard and soft tissue contact zones

14. (newly amended previously presented new claim). An orthopedic implant comprising an implant element for surgical insertion into a bone or bone-related tissue of a patient, said implant element comprising a micro-geometric, repetitive surface pattern in a form of a multiplicity of substantially parallel alternating ridges and grooves, each having an established width in a range of about [of about] 2 to about 25 microns, and an established depth in a range of about 2 to about 25 microns,

whereby said micro-geometric repetitive pattern defines a guide for a promotion of the rate, orientation and direction of growth of colonies of cells of said bone which are in contact with said surface pattern.

15. (previously presented new claim). The implant as recited in Claim 14, in which said implant element comprises a grid-like matrix of said pattern of alternating ridges and grooves.

16. (previously presented new claim). The implant as recited in Claim 14, in which said alternating ridges and grooves are oriented in parallel with a longitudinal axis of said implant.

17. (newly amended previously presented new claim). The implant as recited in Claim 14 [16], in which said alternating ridges and grooves are oriented transversely to said longitudinal axis of said implant.

18. (newly amended previously presented new claim). The implant as recited in Claim 5, in which the surface of said implant element comprises a surface selected from the group of surfaces consisting of hydroxyapatite, RBM roughening, titanium, plasma [,] sprayed, calcium sulfate, biocompatible glass, collagen, growth factor compounds, and combination thereof.

19. (newly amended previously presented new claim). The implant as recited in claim 9, in which said repetitive micro-geometric pattern is [comprises] a product of the process group consisting of laser etching, acid etching, mechanical etching, and photolithography.

Proposed Amended Independent Claim 14

An orthopedic implant comprising an implant element for surgical insertion into a bone or bone-related tissue of a patient, said implant element comprising a micro-geometric, repetitive surface pattern in a form of a multiplicity of substantially parallel alternating ridges and grooves, each having an established width in a range of 2 to 25 microns, and an established depth in a range of 2 to 25 microns,

whereby said micro-geometric repetitive pattern defines a guide for a promotion of the rate, orientation and direction of growth of colonies of cells of said bone which are in contact with said surface pattern.